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STATE FOR OES/IHA AND EUR/UBI USDOC FOR 4212/OECA/JLEVINE

E.O. 12958: N/A TAGS: TBIO ETRD BE

SUBJECT: U.S.-Belgium Confidentiality Agreement Signed

11. (SBU) On April 23, U.S. Food and Drug Administration (FDA) Deputy Commissioner Murray Lumpkin signed a Bilateral Confidentiality Agreement with Piet Vanthemsche, head of

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the recently created Belgian Federal Agency for Medications and Health Products (AFMPS). Deputy Econ Counselor represented the Embassy at the signing. The agreement, which has been under discussion for the past three years, will assure confidential handling of information — including nonpublic, regulatory, and/or business proprietary information — about pharmaceutical production that is shared by the two countries as they verify production standards and quality of medications, as well as cooperate on public information regarding health products.

12. (SBU) The new Agreement can facilitate the production and sharing of drugs and vaccinations, which would be particularly important in the event of an avian flu pandemic. The Agreement also will aid coordination in the fight against counterfeit pharmaceuticals. Trade in counterfeit versions of legitimate pharmaceuticals is expanding rapidly, reportedly overtaking the illegal drug trade in terms of profitability. Unauthorized, ineffective and sometimes lethal versions of prescription medications from aspirin to Viagra are flooding markets, particularly in the developing world. The FDA is pursuing bilateral agreements with European Union member states because this facilitates U.S. information exchange with the European Commission. Priority in negotiating these, however, is given to countries with significant pharmaceutical production capacity.

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